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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,967	02/04/2000	Theodore G. Clark	235.00170101	8124

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/497,967	CLARK ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6,10,11,14,17-21,23,36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5 and 36* is/are allowed.

6)☒ Claim(s) *3,4,6,10,11,14,17-21,23 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 13, 2004 has been entered.

New claim 38 has been added, accordingly, claims 3-6, 10-11, 14, 17-21, 23, 36, and 38 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 3-4, 6, 10-11, 14, 17-21, and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Additionally, this rejection is applied to newly added claim 38.

Applicants are asserting that claim 3 has been amended to recite that the antigenic portion of the I-antigen polypeptide having amino acid sequence SEQ ID NO: 7 comprises amino acids 21-452 of SEQ ID NO: 7. Applicants further assert that claim 4 has been amended to recite that the terminal membrane targeting portion of SEQ ID

NO: 7 is encoded by SEQ ID NO: 19 or 20. Applicants further assert that claim 3, as amended, now recites an antigenic portion of an I-antigen polypeptide comprising an internal amino acid sequence, amino acids 21-452 of SEQ ID NO: 7, and that the specification describes the synthesis of full length and truncated (missing amino acids 1-20 or 453-468) 55 kD I-antigen vectors.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claim 3 has been amended to recite that the antigenic portion of the I-antigen polypeptide having amino acid sequence SEQ ID NO: 7 comprises amino acids 21-452 of SEQ ID NO: 7. However, Applicants are respectfully directed to the claim language. Claim 3 recites "An isolated nucleic acid molecule comprising a polynucleotide ***fragment*** having a nucleotide sequence that encodes an ***antigenic portion*** of an I-antigen..." (Emphasis added). While the remainder of the claim describes the sequence which constitutes as the antigenic portion of the I-antigen, there is no limitation that the claimed nucleic acid fragment must encode this entire fragment (i.e., amino acids 21-452 of SEQ ID NO: 7). As a suggestion, amendment of the claim to recite "An isolated nucleic acid molecule consisting of a polynucleotide fragment which encodes amino acids 21-452 of SEQ ID NO: 7" will be sufficient to overcome this rejection. Alternatively, the transitional phrase of "comprising" may be employed if accompanied with a functional claim limitation of the encoded peptide or protein.

Second, Applicants assert that claim 4 has been amended to recite that the terminal membrane targeting portion of SEQ ID NO: 7 is encoded by SEQ ID NO: 19 or 20. However, each of these sequences are 60 nucleotides in length, and do not encode a full length protein. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since additional nucleotides upstream or downstream of the non-full length fragment will have a profound impact on the activity of the protein, a sixty nucleotide fragment is insufficient to describe the genus.

Finally, Applicants assert that claim 3, as amended, now recites an antigenic portion of an I-antigen polypeptide comprising an internal amino acid sequence, amino acids 21-452 of SEQ ID NO: 7, and that the specification describes the synthesis of full length and truncated (missing amino acids 1-20 or 453-468) 55 kD I-antigen vectors. However, as set forth previously, Applicants sole full length working examples involve a single example of the 55 kD I antigen (SEQ ID NO: 7). Thus, claiming fragments of this example would include numerous structural variants which have not been supported by the disclosure of a single full length working example.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly

variant, a "fragment having a nucleotide sequence that encodes an antigenic portion of an I-antigen" or "at least 50 nucleotides" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a

DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

2. The rejection of claims 4, 6, 14, 17, 19 and 21 under 35 U.S.C. 102(b) as being anticipated by Clark et al is withdrawn in view of Applicants amendment.

3. The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Birkett et al is withdrawn in view of Applicants amendment.

Claims 5 and 36 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
October 27, 2004